

]IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CHARLES T. NEVELS, M.D.,

Defendant.

CIVIL ACTION NO.:

JURY TRIAL DEMANDED

COMPLAINT

Comes now the United States of America and alleges as follows.

I. Nature of the Action

1. This is a civil action to recover treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729–33, and to recover money on an equitable cause of action for unjust enrichment. This action arises out of Defendant Dr. Charles T. Nevels's illegal scheme to knowingly cause false and fraudulent claims for payment for the prescription drug Nuedexta to be presented to federal health care programs. The claims were false and fraudulent because they resulted from kickbacks from Nuedexta's manufacturer to Dr. Nevels, in violation of 42 U.S.C. § 1320a-7b(b), and also because they were for Nuedexta that was not for a medically accepted indication in violation of 42 U.S.C. §§ 1395w-102(e).

II. Jurisdiction and Venue

2. This action arises under the False Claims Act, 31 U.S.C. §§ 3729–33, and the common law.

3. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1345 because the United States is the plaintiff. The Court also has subject-matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1367(a).

4. The Court may exercise personal jurisdiction over Dr. Nevels under 31 U.S.C. § 3732(a) because Dr. Nevels can be found, resides, and transacts business in this district.

5. Venue is proper in the Northern District of Alabama under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because Dr. Nevels can be found, resides, and transacts business in this district, and a substantial part of the events or omissions giving rise to this action occurred in this district.

III. Parties

6. The Plaintiff is the United States, suing on its own behalf and on behalf of the Department of Health and Human Services (“HHS”) and its component agency, the Centers for Medicare and Medicaid Services (“CMS”), which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* (“Medicare”), and

jointly funds Grants to States for Medical Assistance Programs pursuant to Title XIX of the Act, 42 U.S.C. §§ 1396 *et seq.* (“Medicaid”).

7. Defendant Dr. Charles T. Nevels, a psychiatrist, resides in Tuscaloosa, Alabama. During the relevant time period, Dr. Nevels provided medical services, including prescribing medication and recommending that other health care providers prescribe medication, to patients located in this district.

IV. The Medicare and Medicaid Programs

8. The Medicare Program is a federal health insurance program that provides medical benefits, items, and services to beneficiaries aged 65 and older, under 65 with certain disabilities, and of all ages with end-stage renal disease.

9. The Medicare program has four parts, denominated Parts A, B, C, and D. Part A of the Medicare Program covers inpatient procedures performed in the hospital setting. Part B of the Medicare Program authorizes payment of federal funds for medical and other health services, including physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. Part C, also called Medicare Advantage, involves plans with the same benefits as Parts A and B.

10. Medicare Part D, also called the Medicare prescription drug benefit, covers prescription drugs. Medicare beneficiaries obtain Part D benefits through enrollment in either a prescription drug plan, which covers only prescription drugs, or a Medicare Advantage plan, which covers both prescription drugs and medical

services. Part D plans are operated by private companies, often referred to as drug plan sponsors, that are approved by Medicare.

11. Medicare Part D plans exclude from coverage any drugs that are not for a medically accepted indication. 42 U.S.C. § 1395w-102(e).

12. Medicare providers, such as physicians or medical practices, enter into provider agreements to establish their eligibility to participate in the program. To be eligible for payment under the program, physicians or a practice must make certain certifications, including agreeing to abide by Medicare laws and regulations and acknowledging that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws such as the Anti-Kickback Statute.

13. The Medicaid program authorizes federal grants to states for medical assistance to low-income, blind, or disabled persons, or to members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state determines eligible groups, types and ranges of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from accounts that draw on the United States Treasury. The federal share of Medicaid expenditures varies by state and can

fluctuate annually. For instance, in FY2017, the federal government's share for Alabama Medicaid was approximately 70%.

14. In Alabama, providers participating in the Alabama Medicaid program submit claims for services rendered to Medicaid recipients to the Alabama Medicaid Agency for payment.

15. When a provider submits a claim to Alabama Medicaid, the provider is certifying that the services provided are medically necessary. ALA. ADMIN. CODE r. 560-X-1-.18(2)(b).

V. The False Claims Act

16. The False Claims Act, 31 U.S.C. §§ 3729–33, as amended by Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009, 31 U.S.C. § 3729(a)(1)(A-C), provides in pertinent part that any person who:

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
- (C) conspires to commit a violation of subparagraph (A), (B) . . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000. . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.¹

¹ For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amount ranges from a minimum of \$5,500 to a maximum of \$11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, 47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty minimum and maximum have increased with inflation. *See* 28 C.F.R. § 85.5.

17. For the purposes of the False Claims Act, “knowing” and “knowingly”:

- (A) mean that a person, with respect to information—
 - (i) has actual knowledge of the information;
 - (ii) acts in deliberate ignorance of the truth or falsity of the information; or
 - (iii) acts in reckless disregard of the truth or falsity of the information; and
- (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1).

18. The False Claims Act defines “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

VI. The Anti-Kickback Statute

19. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), provides, in pertinent part, that whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1).

20. The Anti-Kickback Statute further provides, “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g).

VII. Dr. Nevels’s Fraudulent Conduct

A. Company A and Nuedexta

21. Company A is a pharmaceutical developer and manufacturer.

22. Company A markets and sells a drug combining two active ingredients, dextromethorphan hydrobromide and quinidine sulfate, under the tradename Nuedexta.

23. In 2010, the U.S. Food and Drug Administration (“FDA”) approved Nuedexta to treat a condition called pseudobulbar affect (“PBA”). PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying.

24. The FDA has not approved the use of Nuedexta to treat any other conditions. Nuedexta has not been shown to be safe and effective in non-PBA types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementia.²

B. Company A's Civil False Claims Act Settlement

25. In September of 2019, Company A reached a civil settlement with the United States resolving False Claims Act claims the United States had against Company A related to Nuedexta. The settlement agreement provides that the United States contends it had claims against Company A based on the following conduct:

- Company A provided remuneration in the form of money, honoraria, travel, and food to certain physicians and other health care professionals (HCPs) to induce those certain HCPs to write prescriptions for Nuedexta. One form of remuneration included Company A's payment to certain HCPs to give talks (commonly known as "speaker programs") about Nuedexta based on the willingness of the HCPs to prescribe Nuedexta.
- Company A implemented a strategy to market Nuedexta to HCPs treating patients in long-term care facilities for uses other than PBA. Non-PBA uses are not FDA approved and are also not medically accepted indications as defined by the statutes and regulations governing the Federal health care programs.

26. To resolve these claims, Company A agreed to pay the United States more than \$95 million.

² FDA Nuedexta Indications and Usage, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021879s000lbl.pdf.

C. Company A's Deferred Criminal Prosecution Agreement

27. At the same time, Company A entered into a deferred criminal prosecution agreement stipulating to the factual basis of a criminal charge that Company A violated the Anti-Kickback Statute by paying a doctor, who is not Defendant Dr. Nevels, hundreds of thousands of dollars in speaker fees and honoraria to induce the doctor to become a high prescriber of Nuedexta to beneficiaries of federal healthcare programs and to recommend that other physicians prescribe Nuedexta to beneficiaries of federal health care programs.

28. As further part of the deferred criminal prosecution agreement, Company A agreed to pay the United States more than \$12 million in monetary penalties and criminal forfeiture.

D. Dr. Nevels's Psychiatric Practice

29. Dr. Nevels is a psychiatrist who has been practicing medicine for over thirty years.

30. Dr. Nevels and his practice Charles T. Nevels M.D. P.C. are enrolled Medicare providers.

31. In 2013, Dr. Nevels signed and submitted an application to revalidate the Medicare enrollment of Charles T. Nevels M.D. P.C. In that application, Dr. Nevels certified on behalf of Charles T. Nevels M.D. P.C. that:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations,

and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

32. Since the early 2000s, Dr. Nevels has contracted with various nursing homes in Alabama to provide psychiatric services to their residents. Dr. Nevels has provided psychiatric services to residents at multiple nursing homes operated by NHS Management, LLC, including Park Manor Health and Rehabilitation, Northway Health and Rehabilitation, Glen Haven Health and Rehabilitation, and Legacy Health and Rehabilitation.

E. Dr. Nevels's Financial Relationship with Company A

33. Company A paid Dr. Nevels to give presentations (sometimes called "speaker programs") about Nuedexta. Between 2015 and 2019, Company A paid Dr. Nevels over \$400,000 to give approximately 178 presentations.

34. Company A also paid Dr. Nevels for the expenses he claimed related to the presentations he gave. For instance, in addition to the speaker fee he received for each presentation, Company A paid Dr. Nevels over \$1,500 for claimed expenses associated with a presentation at The Arrogant Butcher in Phoenix, Arizona, and over \$1,200 for claimed expenses associated with a presentation at the Gamlin Whiskey House in St. Louis, Missouri. Between 2015 and 2019, Company A paid

Dr. Nevels over \$36,000 for claimed expenses associated with his presentations on behalf of Company A.

35. Despite paying Dr. Nevels an average speaker fee of about \$2,200 per presentation during this period, Company A did not want Dr. Nevels adding any special knowledge or expertise to the presentations. The presentation materials were provided by Company A, and Dr. Nevels was not permitted to alter or deviate from them.

36. Dr. Nevels's 2016 speaker agreement with Company A stated: "Speaker must never use Speaker's own slides or other presentation materials for any purpose . . . during the course of a Speaker Program." Dr. Nevels's 2019 agreement similarly provided: "Speaker shall use only [Company A]-approved presentation materials. . . . Speaker agrees not to alter or change any [Company A] materials and/or presentations and to present the material in its entirety."

37. Beyond the speaker agreements themselves, Company A repeatedly reminded Dr. Nevels that he should not provide any of his own expertise during a presentation. For instance, a 2019 email instructed Dr. Nevels that "**As a Speaker for [Company A]** . . . *Do not provide any information based on your own clinical experience.*" (Emphasis in original.)

38. Dr. Nevels's resume did not indicate that he had any special experience or expertise regarding PBA or Nuedexta, such as participating in clinical trials or

publishing studies. Dr. Nevels's CV, submitted to Company A at the time he was selected to be a speaker, did not contain the terms "PBA" or "Nuedexta," or otherwise indicate he had special knowledge of these matters. Therefore, having Dr. Nevels deliver Company A's presentation materials did not add special weight to the presentations.

39. Although Dr. Nevels's presentations were nominally intended to promote awareness about Nuedexta, based on Company A's records, Dr. Nevels repeatedly gave presentations where there were only a few attendees. Company A paid Dr. Nevels approximately \$17,000 in speaker fees and claimed expenses to give presentations where Company A's records show the program had no attendees. For instance, in November 2016, Company A paid Dr. Nevels a \$2,000 speaker fee to give a presentation in Decatur, Alabama, that Company A's records show had no attendees.

40. Company A also paid Dr. Nevels approximately \$41,000 in speaker fees and claimed expenses to give presentations where Company A's records show the program had a single attendee. For instance, in March 2019, Company A paid Dr. Nevels a \$4,000 speaker fee for a presentation in Raleigh, North Carolina, that Company A's records show had a single attendee.

41. The documented attendees at Dr. Nevels's presentations repeatedly included Company A employees whose presence provided no promotional benefit

to Company A. Some Company A employees sat through multiple identical presentations given by Dr. Nevels. For instance, in September 2016, Company A paid Dr. Nevels a \$2,400 speaker fee to give a presentation in St. Louis, Missouri where the only documented attendee was a St. Louis-based Company A sales representative. The next day, this sales representative attended the same presentation by Dr. Nevels three more times. In one presentation, he was one of two documented attendees, and in another, he was one of three attendees.

42. The documented number of attendees was further inflated by having people that Dr. Nevels collaborated with in giving Company A presentations go as attendees to other substantively identical presentations they were not collaborating on with Dr. Nevels.

43. For instance, in July 2016, a South Carolina-based Company A sales representative collaborated with Dr. Nevels on a presentation given in Columbia, South Carolina. In October 2016, this sales representative watched Dr. Nevels give a substantively identical presentation as one of four attendees. Then on three consecutive days in November 2016, this sales representative watched Dr. Nevels give the same presentation from July and October three more times as an attendee. At one presentation, the sales representative was one of three attendees; Company A paid Dr. Nevels a \$2,400 speaker fee for this presentation. At another

presentation, the sales representative was the only attendee; Company A paid Dr. Nevels a \$1,400 speaker fee for this presentation.

44. If Company A employees and individuals who collaborated with Dr. Nevels on other Company A presentations are subtracted from the number of attendees, Company A frequently paid Dr. Nevels to give presentations that had no or few legitimate attendees. Company A paid Dr. Nevels approximately \$23,000 in speaker fees and expenses for presentations that only had Company A employees or speaker collaborators as attendees. Company A paid Dr. Nevels approximately \$46,000 in speaker fees and expenses for presentations with only one attendee who was not an Company A employee or speaker collaborator.

45. Company A paid Dr. Nevels even when he did not give presentations. Company A paid Dr. Nevels \$15,550 in speaker fees for presentations that were canceled and not given.

F. Origin of Dr. Nevels's Financial Relationship with Company A

46. The financial relationship between Dr. Nevels and Company A started with Company A providing Dr. Nevels with valuable patient referrals in return for Nuedexta prescriptions.

47. In 2011, SC was the Company A sales representative assigned to market Nuedexta to Dr. Nevels. That year, SC first nominated Dr. Nevels to become a paid speaker for Company A.

48. The following year, 2012, SC stated to his supervisor, “Dr. Nevels is a speaker for us and we have utilized him in many of his facilities. Every facility that I have used him in, he has written [Nuedexta prescriptions] for patients identified at the presentations. . . . He is currently looking for better ways to identify patients in his facilities with the help of his social workers and [nurses].”

49. Thereafter, SC took it upon himself to help identify patients for Dr. Nevels and to generate valuable patient referrals for Dr. Nevels.

50. SC regularly went to the nursing homes where Dr. Nevels worked, and persuaded staff to refer patients to Dr. Nevels. According to SC, he went to the nursing home staff, stating that “Dr. Nevels will be here later this week,” and “asked if charts could be pulled for any dementia patients etc.” to see Dr. Nevels. SC explained to colleagues that this tactic “is giving [Dr. Nevels] additional residents to see and the home is able to treat potential PBA patients with appropriate medication and stay within CMS regulation” discouraging the use of anti-psychotic drugs. “It’s a win all around.”

51. Using this tactic, SC became one of Company A’s top sales representatives, winning Company A’s President’s Circle of Excellence award with 1,100% sales growth in 2012, winning Company A’s Million Dollar Sales Club award in 2013, and receiving several promotions, largely as a result of Dr. Nevels’s prescriptions.

52. In April 2014, SC reported to his supervisors that Dr. Nevels's prescribing of Nuedexta had declined when SC had stopped going to nursing homes and persuading staff to refer patients to Dr. Nevels. SC stated that he would reverse the decline. SC stated that he told Dr. Nevels he "would refocus [his] efforts back in [Dr. Nevels's] homes using his schedule to go to the homes ahead of him." SC reported that Dr. Nevels responded by stating, "our system has worked well for a while." SC stated that Dr. Nevels said "he has no problem writing Nuedexta for any resident that is put in front of him, he just needs the names to see them."

53. In May 2014, SC further explained to a fellow Company A sales representative, "I helped [Dr. Nevels and another doctor] to understand their need to have me in their facilities identifying residents for them to see. This approach works better for them because they are [geriatric psychiatrists] and need the referrals. I helped them see beyond just the writing of Nuedexta. It was a chance to build their base of business."

54. Continuing into the relevant time period, under what Dr. Nevels called "our system," Dr. Nevels continued to receive unlawful remuneration from Company A in the form of patient-referral services, in return for prescribing and recommending Nuedexta. Dr. Nevels's practice manager sent Dr. Nevels's monthly schedule to Company A salespeople, so the salespeople could go to nursing homes ahead of Dr. Nevels and persuade staff to refer patients to Dr. Nevels.

G. Dr. Nevels's Nuedexta Prescribing

55. Dr. Nevels was responsible for a high volume of Nuedexta prescriptions. From 2015 to 2019, Dr. Nevels was responsible for Nuedexta prescriptions to over 490 different Medicare beneficiaries. These beneficiaries received over 13,000 Nuedexta prescriptions providing over 220,000 days' supply of Nuedexta. On average, each of these beneficiaries received approximately 450 days' worth of Nuedexta. In total, Medicare paid over \$6 million for Nuedexta prescriptions written for Medicare beneficiaries treated by Dr. Nevels.

56. In 2015, Medicare paid approximately \$1.3 million in total for Nuedexta prescriptions for all the Medicare beneficiaries in the State of Alabama. That same year, Medicare paid approximately \$740,000 for Nuedexta prescriptions written for Alabama Medicare beneficiaries treated by Dr. Nevels. The amount paid by Medicare for Nuedexta prescriptions for patients seen by Dr. Nevels accounted for over 50% of Medicare's total 2015 expenditure for Nuedexta prescriptions for all Alabama beneficiaries.

57. Between 2015 and 2019, Dr. Nevels was responsible for approximately 20% of all Nuedexta prescriptions written for Medicare beneficiaries in Alabama. During this same period, Alabama consistently had more Nuedexta prescriptions written per Medicare beneficiary than almost every other state or territory.

58. Between 2015 and 2019, Alabama Medicaid paid over \$800,000 for Nuedexta prescriptions written for Medicaid beneficiaries treated by Dr. Nevels.

H. Dr. Nevels's Not-Indicated Prescriptions

59. Dr. Nevels was also responsible for not-medically-indicated and not-medically-necessary Nuedexta prescriptions for patients who did not have symptoms consistent with PBA and had no prior PBA diagnosis. Nuedexta prescribed in these non-PBA contexts failed to meet the definition of a Medicare Part D drug, because non-PBA uses are not medically accepted indications, *see* 42 C.F.R. § 423.100 (defining Part D drug as one “used for a medically accepted indication”), and not medically necessary.

60. Dr. Nevels also regularly failed to document in patient medical records what, if any, effect the Nuedexta he was responsible for prescribing had on the patient and any behaviors.

61. Dr. Nevels's Nuedexta prescriptions to patient RA provide an example of Dr. Nevels's medically unnecessary prescribing practices.

62. RA was admitted to Park Manor Health and Rehabilitation in 2016.

63. On April 24, 2017, Dr. Nevels had an initial psychiatry consult with RA. RA presented with appropriate appearance and demeanor, thought processes, and speech. He was oriented to person, place, time, and situation, with intact memory and intellect. He had a flat affect and a depressed mood. Dr. Nevels

diagnosed depression secondary to medical illness and anxiety secondary to medical illness.

64. On May 12, 2017, Dr. Nevels saw RA for a follow-up psychiatric consult. Dr. Nevels noted no new symptoms and stated that RA was in a joking mood and the staff had reported no new symptoms. Dr. Nevels's clinical impression was unchanged; depression secondary to medical illness and anxiety secondary to medical illness. In the recommendations section, Dr. Nevels wrote: "Continue current meds. Stable and present[.]"

65. On June 13, 2017, a note was entered in the physician's orders section of RA's medical records, stating: "Add Pseudobulbar Affective Disorder F48.2, Add Nuedexta 20-10 1 cap a [day] for 7 days then [discontinue] [and] add Nuedexta . . . 20-10 1 cap [twice a day], PO [DH]/Charles Nevels."

66. DH is a nurse practitioner who had a collaborative practice agreement with Dr. Nevels and worked under his supervision.

67. That same day, claim number 1716529441141689979110 was submitted to RA's Medicare Part D plan. It was a claim for Nuedexta that listed Dr. Nevels as the referring provider. Medicare paid approximately \$97 for this claim.

68. Nothing in RA's medical record indicates that he began experiencing the systems consistent with PBA between Dr. Nevels's May consult and the June Nuedexta prescription.

69. On August 24, 2017, Dr. Nevels had a follow-up psychiatry consult with RA. Dr. Nevels listed Nuedexta as one of RA's current medications. In the comments, Dr. Nevels wrote: "Continues to have staff accompany him to [illegible] due to behavioral issues. He laughs when behaviors are mentioned." In the impression section, Dr. Nevels wrote depression secondary to medical illness and anxiety secondary to medical illness. In the recommendations section, Dr. Nevels wrote: "Continue current meds. Pt. thinks it is funny that he must be accompanied by others. Behaviors are purposeful."

70. In this visit note, Dr. Nevels makes no reference to a PBA diagnosis or involuntary laughing or crying. Dr. Nevels also made no notes regarding whether Nuedexta had an effect on any symptoms.

71. In July 2018, RA was admitted to a hospital for treatment. The hospital discontinued RA's Nuedexta prescription.

72. Following RA's discharge from the hospital back to Park Manor Health and Rehabilitation, Dr. Nevels ordered that RA be placed back on Nuedexta.

73. Between June 2017 and the end of 2018, Dr. Nevels caused the submission of close to 40 claims for Nuedexta prescriptions to be submitted to RA's

Part D plan. In total, Medicare paid approximately \$17,000 for RA's Nuedexta prescriptions. The claim number and claim date for each prescription is set out below:

Claim Number	Claim Date
1716529441141689979110	06/14/2017
1717153205841839999110	06/20/2017
1718230417842229999110	07/01/2017
1719632238562059999110	07/15/2017
1720933822691209999110	07/28/2017
1722139684760539999110	08/09/2017
1723640802341529999110	08/24/2017
1725139259581469999110	09/08/2017
1726541251112159999110	09/22/2017
1728626732772099999110	10/13/2017
1729725252192199999110	10/24/2017
1731146520491899999110	11/07/2017
1732152621150909999110	11/17/2017
1733730276500889999110	12/03/2017
1734730871940749999110	12/13/2017
1736334233871679999110	12/29/2017
1801239270872229999110	01/12/2018
1802628880912009999110	01/26/2018
1807424700802209999110	03/15/2018
1809339627501969999110	04/03/2018
1811329970452089999110	04/23/2018
1812933330021599999110	05/09/2018
1814130086711099999110	05/21/2018
1815532114711459999110	06/04/2018
1817248595812159999110	06/21/2018
1818048722381919999110	06/29/2018
1819127303640419999110	07/10/2018
1820031569912249999110	07/19/2018
1823934344412219989110	08/25/2018
1824025592462019989110	08/28/2018
1824926080180889999110	09/06/2018
1826025074461509999110	09/17/2018

1827125749170449999110	09/28/2018
1828127223421919999110	10/08/2018
1829331633291629999110	10/20/2018
1830831044951489999110	11/04/2018
1832332352851199999110	11/19/2018
1833728775320609999110	12/03/2018
1835134040030459999110	12/17/2018

74. The Nuedexta that Dr. Nevels ordered RA to be treated with, and consequently was billed to Medicare Part D, was not for a medically accepted indication and not reasonable and necessary for the diagnosis or treatment of an illness or injury because RA did not have PBA or its symptoms.

F. Dr. Nevels's Knowledge

75. Dr. Nevels was aware of the requirements of the Anti-Kickback Statute. As an enrolled Medicare provider, Dr. Nevels was required to certify that he understood that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with the Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b).

76. In addition, in speaker agreements with Company A, Dr. Nevels warranted that he would comply with the Anti-Kickback Statute. While Dr. Nevels's financial relationship with Company A did not actually comply with the Anti-Kickback Statute, Dr. Nevels's warranty of compliance in the speaker agreements show his knowledge of the statute.

77. Dr. Nevels knowingly and willfully solicited and received unlawful remuneration directly and indirectly from Company A in the form of speaker fees, expense reimbursement, and other in-kind remuneration such as free travel, accommodation, and valuable patient-referral services.

78. Dr. Nevels solicited and received this unlawful remuneration in return for ordering and arranging for ordering Nuedexta for Medicare and Medicaid beneficiaries.

79. For the purposes of the Anti-Kickback Statute, Dr. Nevels's knowledge and willfulness is shown in several ways. The large amount in absolute terms that Company A paid Dr. Nevels, over \$400,000 in speaker fees alone, is evidence that Dr. Nevels's arrangement with Company A was a financial inducement to increase Dr. Nevels's use of Nuedexta.

80. Further, Company A's payments to Dr. Nevels were untethered from the marketing benefits Dr. Nevels was nominally providing through his presentations. Company A repeatedly paid Dr. Nevels to give presentations to no attendees or a single attendee, and paid Dr. Nevels to give the same presentation multiple times to the same Company A sales representatives.

81. It is also clear that Dr. Nevels was aware that Company A was not paying him for his specific expertise or knowledge, as he was not permitted to alter the materials provided by Company A or provide information based on any clinical

knowledge or experience, and his resume did not indicate he had any special experience or expertise regarding PBA or Nuedexta.

82. Dr. Nevels's own actions are also evidence of his knowledge and willfulness. Dr. Nevels was responsible for a large volume of Nuedexta prescriptions in both absolute terms and in relative terms compared to other similarly situated providers. Dr. Nevels also repeatedly caused Nuedexta to be prescribed to beneficiaries who did not have PBA and had no medical need for Nuedexta. These actions are consistent with a provider causing Nuedexta to be prescribed in exchange for remuneration rather than based on the medical needs of patients.

VIII. Counts

Count I

Causing the Submission of False and Fraudulent Claims to Medicare and Medicaid in Violation of 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B)

83. Plaintiff incorporates by reference paragraphs 1-85 of this Complaint as if fully set forth. During the time period from 2015 to the present, Defendant Dr. Charles T. Nevels knowingly presented and caused to be presented materially false and fraudulent claims for payment to the United States, including claims for reimbursement by Medicare Part D plan sponsors and the Alabama Medicaid program, that were materially false and fraudulent because they resulted from kickbacks, in violation of 42 U.S.C. § 1320a-7b(b) and (g), and also because they

were for drugs that were not medically indicated in violation of 42 U.S.C. §§ 1395w-102(e).

84. These claims were presented and caused to be presented with actual knowledge of their falsity and fraudulence, or with reckless disregard or deliberate ignorance of whether or not they were false and fraudulent.

85. A list of each such false claim submitted to the Medicare and Medicaid programs identified by claim number and claim date is attached as Exhibit A.

Count II

Unjust Enrichment

86. Plaintiff incorporates by reference paragraphs 1-85 of this Complaint as if fully set forth.

87. During the time period from 2015 to the present, the United States paid claims for payment, including claims for reimbursement by Medicare Part D plan sponsors and the Alabama Medicaid program, for Nuedexta. These claims for payment resulted from kickbacks and were for drugs that were not medically indicated. A list of these claims for payments is attached as Exhibit A.

88. Defendant Dr. Charles T. Nevels received money from Company A for causing these claims for payment to be presented to the United States. As a result, he was unjustly enriched at the expense of the United States and is liable to pay such amounts to the United States.

IX. Prayer for Relief

The United States requests that judgment be entered in its favor and against Defendant as follows:

- (A) On Count I, an award for treble the United States' damages, together with the maximum civil penalties allowed by law;
- (B) On Count II, an award of the amount by which Defendant was unjustly enriched; and
- (C) An award of pre-and post-judgment interest, costs, and such other relief as the Court may deem just and proper.

The United States demands a jury trial of all issues so triable.

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